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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,438	11/13/2001	Bernard A. Hausen	032405-059 US	7508

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CARDICA, INC.
900 SAGINAW DRIVE
REDWOOD CITY, CA 94063

EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,438

Applicant(s)

HAUSEN ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-57 is/are pending in the application.
- 4a) Of the above claim(s) 19-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-18,45,48,50,51,53,56 is/are rejected.
- 7) ☒ Claim(s) 3,46,47,49,52,54,55,57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/20/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. That is, "said anvil" lacks antecedent basis.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 8, 13, 14, 16, 48, 50, 51, 53, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor et al. (6,036,641). Taylor et al. disclose, in figures 4A and 11 and in col. 11, line 12 to col. 12, line 46 and col. 18, line 54 to col. 19, line 24, a method as claimed for performing beating-heart closed-chest surgery, where the method includes, inter alia, creating a point of entry into the thoracic cavity via a sub-xyphoid approach to an intrapericardial space, stabilizing the heart by inserting through the point of entry an integrated stabilizer (1) connected to a tool (55),

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performing a distal anastomosis with the tool while the heart is beating, attaching a graft vessel (59) to an opening in a target vessel (56), attaching a clamp assembly (58) to the distal end of the graft vessel, and securing the integrated stabilizer to the heart by exerting a force against both the heart (via a linkage, 3) and the chest wall (via a retractor), where the integrated stabilizer includes a shell (e.g. 1 in fig. 4A) having an open space (22) therein and a substantially oval perimeter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 6, 7, 10-12, 15, 17, 18, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. Taylor et al. disclose the invention substantially as claimed. They disclose placing an end of a tool (57/58) substantially normal to the target vessel, splitting the tool (i.e., separating 57 from 58) to release the graft vessel, and deploying an anastomosis device (61). However, Taylor et al. do not disclose

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performing a proximal anastomosis between the graft vessel and another target vessel, deploying a trocar port into the point of entry, measuring the distance between an proximal anastomosis site and a distal anastomotic site, extending an opening in the pericardium from the aorta to the apex of the heart, slicing the distal end of the graft, viewing the anastomosis sites during the procedure, and performing an additional distal anastomosis. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to deploy a trocar port into the point of entry, slice the distal end of the graft, and view the anastomosis sites during the procedure. It is well-known in the art to apply a trocar port in order to make the opening in the thoracic cavity for minimally-invasive surgery. Slicing the distal end of the graft would prepare a straight, "clean" edge at the end for proper attachment of the graft to the target vessel. Viewing anastomosis sites would allow proper assessment of the tissues to be worked on and would provide visual feedback during performance of the method. It would be a matter of design choice to perform a proximal anastomosis between the graft vessel and another target vessel, measuring the distance between a proximal anastomosis site and a distal anastomotic site, extending an opening in the pericardium from the aorta to the apex of the heart, and performing an additional distal anastomosis. The choice for performing a proximal anastomosis or an additional distal anastomosis would be dependent upon the condition and therapeutic demands of a patient. The choice for extending an opening in the pericardium would be dependent upon the location of the anastomosis, where an extended opening would allow better access to the target site. The choice for measuring the distance between the proximal

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anastomosis and the distal anastomotic site would be dependent upon surgical demands that may require sizing available grafts.

Allowable Subject Matter

7. Claims 3, 46, 47, 49, 52, 54, 55, and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a method as claimed for performing beating-heart closed-chest surgery, where the method includes, inter alia, attaching a graft vessel to a target vessel with stapling, where anastomosis is sutureless, where at least one clip from the integrated stabilizer engages the heart, where the tool is positioned substantially within the open space of the integrated stabilizer, where an endoscope and a light source are included with the integrated stabilizer, and where the tool includes an anvil inserted into the lumen of the target vessel.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

9. Applicant's arguments with respect to claims 1-3, 5-8, 10-18, and 45-57 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Altman et al. (6,296,630) teaches beating-heart surgery.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

September 20, 2004